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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SERIAL NO.: 08/765,695 § DOCKET NO. P-01525US0
FILING DATE: JULY 25, 1997 § EXAMINER:
APPLICANT: LARS ABRAHMSSEN, § R. SCHWADRON
ET AL. §
TITLE: "CONJUGATE BETWEEN §
A MODIFIED SUPERANTIGEN §
AND A TARGET-SEEKING §
COMPOUND AND THE USE OF §
THE CONJUGATE" §



APR 15 1999
GROUP 180

Assistant Commissioner for Patents
Washington, D.C. 20231

SUPPLEMENTAL IDS TRANSMITTAL LETTER

Dear Sir:

Applicants respectfully submit the attached PTO Form 1449 and copies of all cited references.

Applicants respectfully assert that these materials are **not** material under 37 CFR § 1.56 to the subject matter claimed in this case and its parent cases. These materials relate to arguments and prior art submitted to the European Patent Office in favor of, and in opposition to, patenting claims related to the use of superantigens (in particular staphylococcal enterotoxins) *in vivo* to treat tumors. In particular, the issues focus on the use of unconjugated (so-called "naked" or "nude") and unmutated (wild-type) staphylococcal enterotoxins to treat, in particular, MHC Class II expressing

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 on <u>4-9-99</u>	
<u>Linda A. Bourg</u> Signature	<u>4-9-99</u> Date

tumors. The arguments and art include general statements, but relate directly to enablement and patentability issues particularly related to the enablement and patentability of the particular European Patent (Number EP-B-444186). This includes detailed arguments regarding particular experiments disclosed in the patent specification. These materials' disclosures (including arguments, teachings, suggestions, and prior art) particularly focus on issues related to the particular aspects of the specification of the European Patent and to the use of un-conjugated wild-type staphylococcal enterotoxins.

Unlike the subject matter of these materials, the subject matter in the above-referenced case relates exclusively to superantigens (including, for example, staphylococcal enterotoxins) that are mutated and/or conjugated to target seeking moieties (e.g., antibodies). Indeed, the point of the claimed invention is the mutation and/or conjugation of superantigens in order to overcome limitations with the use of wild-type unconjugated superantigens.

The submitted IDS materials highlight the limitations in using un-conjugated and un-mutated (wild-type) superantigens. Indeed, arguments in the materials that are adverse to patenting the use of un-conjugated and wild-type superantigens actually favor arguments for conjugating and/or mutating superantigens in order to overcome the limitations of "naked" superantigens.

The attached IDS materials do not in any way disclose, suggest or teach, either alone or in any combination, the conjugation of superantigens (e.g., to target-seeking moieties) to overcome problems associated with "naked" superantigens. Furthermore, attached IDS materials do not in any way disclose, suggest or teach, either alone or in any combination, the mutation of superantigens (e.g., to reduce MHC Class II binding) to overcome problems associated with wild-type superantigens. Accordingly, these materials cannot create a *prima facie* case under 37 C.F.R. § 1.56

of obviousness against the claimed subject matter of the present case since they do not disclose, suggest or teach this subject matter.

Also under 37 C.F.R. § 1.56, these materials cannot be relevant to the file history in this case since, so far, there is no substantive file history. Moreover, applicants respectfully note that these IDS materials will not become relevant to the file history in this case. Nothing more than the general arguments in the IDS materials could relate to the prosecution of this case. The criticisms of specific European Patent experiments do not apply to this specification. Further, there is nothing in the attached IDS materials, including the general statements, that is more than cumulative to any prior art already submitted in this case.

However, this IDS is being submitted nonetheless in an abundance of caution in view of complete disclosure.

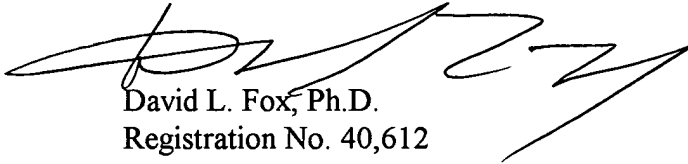
The Examiner is encouraged to call the undersigned should there be any questions or concerns in this matter.

Applicants respectfully petition the Commissioner for any extension of time necessary to render this submission timely.

Because this submission is being made before the mailing date of a first substantive Office Action in this case, it is timely under 37 C.F.R. § 1.97(b)(3). However, the Commissioner is hereby

authorized to charge the standing account of Fulbright & Jaworski L.L.P., account number 06-2375
for any fees due in this matter.

Respectfully submitted,



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Date: 8 April 1999

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